

We Claim:

1. An intraluminal material removal system comprising: a drive shaft that is rotatable and translatable; a drive system operably coupled to the drive shaft in proximity to its proximal end for rotating the drive shaft at rotational speeds in excess of 500 rpm; and a composite cutter assembly mounted in proximity to a distal end of the drive shaft, the cutter assembly comprising multiple cutting surfaces, the multiple cutting surfaces having at least two different configurations.
2. The system of claim 1, wherein the cutter assembly comprises a distal, fixed diameter cutter and a proximal, adjustable diameter cutter in proximity to one another.
3. The system of claim 2, wherein at least one of the cutters is provided with ports that communicate with a sealed lumen that extends proximally from the cutter assembly.
4. The system of claim 3, additionally comprising a vacuum source and aspirate collection system connectable to the sealed lumen for aspiration through the ports.
5. The microsurgical system of claim 3, additionally comprising an infusion system connectable to the sealed lumen for infusion through the ports.
6. The system of claim 1, wherein the drive system is selectively bi-directional and is capable of selectively rotating the drive shaft in opposite directions.
7. The system of claim 2, wherein the proximal, adjustable diameter cutter has a first diameter when rotated in a first direction and a second diameter, different from the first diameter, when rotated in a second direction opposite the first direction.
8. The system of claim 5, wherein the proximal, adjustable diameter cutter has a plurality of pivotable cutting blades.
9. The system of claim 1, additionally comprising: a hollow sheath having a diameter larger than the drive shaft diameter and forming a lumen between an inner surface of the sheath and an outer surface of the drive shaft, the cutter assembly additionally comprising a plurality of ports having an open configuration in communication with the lumen.

10. The system of claim 1, wherein the drive shaft has a flexible, hollow, helical configuration, and comprises at least one section having a predominantly left-lay helical configuration and at least a second section having a predominantly right-lay helical configuration.
- 5 11. The system of claim 1, additionally comprising an advancer system for axially displacing the drive shaft and cutter assembly.
12. The system of claim 1, additionally comprising a flexible guidewire.
13. The system of claim 1, additionally comprising a magnetic coupler for operably coupling the drive system to the drive shaft.
- 10 14. The system of claim 1, additionally comprising a temperature monitor provided in proximity to the cutter assembly.
15. The system of claim 1, additionally comprising a control unit capable of receiving operator input and calculating and implementing automated operating conditions based on the operator input.
- 15 16. An intraluminal material removal system comprising: a drive shaft that is rotatable and translatable; a drive system operably coupled to the drive shaft in proximity to its proximal end for rotating the drive shaft at rotational speeds in excess of 500 rpm; and an adjustable diameter cutter assembly mounted at a distal end of the drive shaft, the cutter assembly comprising a plurality of pivotable cutting blades that are selectively adjustable between a smaller diameter condition and a larger diameter condition by changing the direction of rotation of the drive shaft.
- 20 17. A material removal system comprising: a drive shaft that is rotatable and translatable; a drive system operably coupled to the drive shaft in proximity to its proximal end for rotating the drive shaft; a cutter assembly mounted at a distal end of the drive shaft comprising multiple cutting surfaces and ports that communicate with a sealed lumen extending proximally from the cutter assembly; and a temperature monitor provided in proximity to the cutter assembly.
- 25 18. A method for removing material from the interior of a lumen using a material removal system having a fixed diameter material removal device and an adjustable diameter material removal device, comprising: rotating the material
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removal system in a first direction while advancing it through material to be removed in a first pass in which the fixed diameter material removal device is the primary material remover, translating the material removal system in an antegrade direction for a subsequent pass, and rotating the material removal system in a second direction, opposite the first direction, while advancing it through the material to be removed in a subsequent pass in which the adjustable diameter material removal device is in an expanded condition and is the primary material remover.

19. An intraluminal material removal system comprising a cutter assembly and a guiding catheter, wherein the guiding catheter includes an occluding balloon positioned proximal to the cutter assembly such that inflation of the occluding balloon leads to reversal of blood flow direction proximal to the cutter assembly.